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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,636

07/15/2004

John George Catalano

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12/21/2006

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B475

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/21/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/501,636

Applicant(s)

CATALANO ET AL.

Examiner

Robert Shiao, Ph. D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-17,19,21,28,29,34-42,44-48,51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/02/05, 7/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the provisional application: 60/349,812 with a filing date 01/17/2002.
2. Amendment of claims 1, 21, 45-48, 51 and 52, cancellation of claims 2-4, 18, 20, 22-27, 30-33 and 43 in the amendment filed on November 11, 2006, is acknowledged. Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statements, filed on July 15, 2004, and September 02, 2005 has been considered. Please refer to Applicant's copies of the 1449's submitted herein.

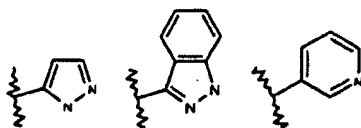
Responses to Election/Restriction

4. Applicant's election of Group I claims (i.e., 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52, in part), in the reply filed on November 10, 2006, is acknowledged. An elected species of Example 3, i.e., Benzyl (2S)-2-[[[(3S)-3-([(benzylcyclopentyl)oxy]carbonyl)amino]-2-oxoheptanoyl]amino]propanoate, is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

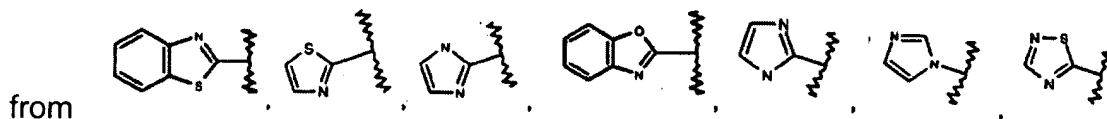
Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are pending in the application. The scope of the invention of the elected subject matter is as follows.


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Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52, in part, drawn to compounds/compositions of formula (I), wherein the heteroaryl or heterocyclyl of the



variable X^2 is selected from thereof; the heteroaryl of the variable Q^3 is selected



or  thereof; the variables R^1 - R^4 or D independently do not represent heteroaryl or heterocyclyl, the variables R^1 - R^4 or D independently are not substituted with heteroaryl or heterocyclyl, and their methods of use.

Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52, in part, embraced in above elected subject matter, are prosecuted in the case. Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52, in part, not embraced in above elected subject matter, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using compounds of formula (I) treating osteoporosis, does not reasonably provide enablement for using compounds of formula (I) treating a disorder without limitation (i.e., no named disease). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case:

The nature of the invention

The nature of the invention of claims 47-48 is drawn to intent methods of use using a compounds of formula (I) treating a disorder without limitation (i.e., no named disease).

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face. Bender et al. disclose similar pyrazole compounds treating osteoporosis, see US 5,948,777.

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

Applicants are claiming intent methods of use using compounds of formula (I) effective to "treating a disorder" without limitation (i.e., no named disease).

As such, the specification fails to enable the skilled artisan to use the compounds of claims effective to "treating a disorder" without limitation (i.e., no named disease).

In addition, there is no established correlation between *in vitro* activity and accomplishing treatment of "treating a disorder" without limitation (i.e., no named disease), and those skilled in the art would not accept allegations in the instant specification to be reliable predictors of success, and those skilled in the art would not be able to use the compounds of formula (I) since there is no description of an actual method wherein "treating a disorder" without limitation (i.e., no named disease) in a host is treated.

Hence, one of skill in the art is unable to fully predict possible results from the administration of the compounds of formula (I) due to the unpredictability of the "treating a disorder" without limitation (i.e., no named disease). The "treating a disorder" without limitation (i.e., no named disease) is known to have many obstacles that would prevent one of ordinary skill in the art from accepting treating regimen on its face.

The amount of direction or guidance present and the presence or absence of working examples

The only direction or guidance present in the instant specification is the listing of *in vitro* or *in vivo* of Cathepsin inhibitory activity in terms of IC_{50} of rats or human examples, see pages 150-153 of the specification. There are no *in vivo* working

examples present for the "treating a disorder" without limitation (i.e., no named disease) by the administration of compounds of the instant invention.

The breadth of the claims

The breadth of the claims is methods of use of the instant compounds effective to "treating a disorder" without limitation (i.e., no named disease).

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what "treating a disorder" without limitation (i.e., no named disease)" would be benefited (i.e., treated) by the administration of the instant compounds of formula (I) of the instant invention and would furthermore then have to determine which of the claimed methods of use would provide treatment of a disease, if any.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which methods of use exhibit the desired pharmacological activity and which diseases would benefit from this activity. Thus, the specification fails to provide sufficient support of the broad use of the pharmaceutical compounds of the instant claims 47-48 for the "treating a disorder" without limitation (i.e., no named disease).

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As a result necessitating one of skill to perform an exhaustive search for which "treating a disorder" without limitation (i.e., no named disease)", can be treated by what pharmaceutical compounds of the instant claims in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success. This rejection can be overcome by incorporation of the treated diseases (i.e., named disorders or named diseases on page 3) into claim 47-48 respectively, would obviate the rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are rejected under 35

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U.S.C. 103(a) as being obvious over Catalano et al. US 2005/0043368 A1. Catalano et al. '368 is 102(e) reference.

The applied reference has a common inventor or assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

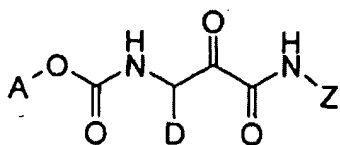
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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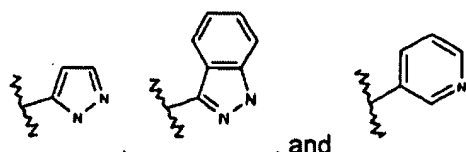
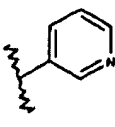
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Applicants claim compounds/composition and methods of use of formula (I), i.e.,



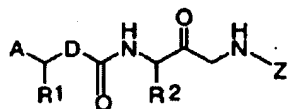
, wherein the variable A represents $(Q^3)-(Q^2)_n-(Q^1)-(Q)_m$ - and the variable Q^3 represents aryl or heteroaryl (e.g., thiazole, imidazole), the variable Z represents $(X)p-(X^1)q-(Q^1)-(X^2)-$ and the variable X^2 represents aryl or

heteroaryl (e.g., , and ), see claim 1. Applicants compounds are for treating osteoporosis, see claim 1, 46 and 51 respectively.

Dependent claims 5-17; 19, 21, 28-29, 34-42, 44-48 and 51-52 further limit a number of variable, i.e., m is 0 or 2.

Determination of the scope and content of the prior art (MPEP §2141.01)

Catalano et al. '368 disclose a compounds/composition and method of use of



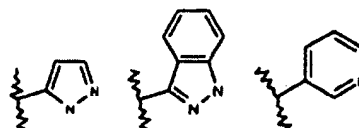
formula (I), i.e., $(Q^3)_p-(Q^2)_n-(Q^1)-(Q)_m-$, wherein the variable A represents $(Q^3)_p-(Q^2)_n-(Q^1)-(Q)_m-$, and the variable p, n or m is 0 independently, Q^1 represents aryl, heteroaryl (i.e., imidazole) or heterocyclyl, and the variable Z represents $(X^1)_q(X^2)$, the variable q is 0-2, and the variable X^2 represents aryl, heteroaryl or heterocyclyl, see columns 43-44. Catalano et al. compounds are used for treating osteoporosis, see column 46.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

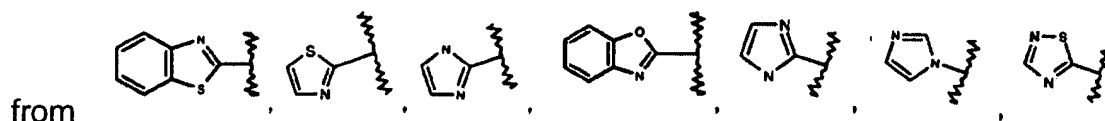
The difference between the instant claims and Catalano et al. is that the the variable Q^1 of Catalano et al. represents aryl, heteroaryl or heterocyclyl, while the instant claims represents aryl or heteroaryl at the same position.


Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 prima facie obvious **because** one would be motivated to employ Catalano et al. compounds/compositions and methods of use to obtain the instant compounds/ compositions and methods of use, wherein the heteroaryl or



heterocyclyl of the variable X^2 is selected from thereof; the heteroaryl of the variable Q^3 is selected



or  thereof; the variables R^1 - R^4 or D independently do not represent heteroaryl or heterocyclyl, the variables R^1 - R^4 or D independently are not substituted with heteroaryl or heterocyclyl. Dependent claims 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are also rejected along with claim 1 under 35 U.S.C. 103(a).

The motivation to obtain the claimed compounds derives from known Catalano et al. compounds/compositions would possess similar activity (i.e., treating osteoporosis) to that which is claimed in the reference.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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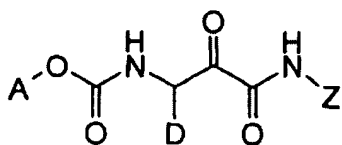
1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

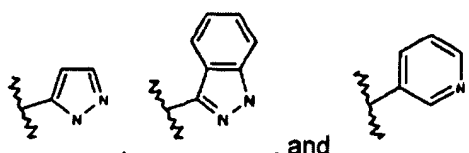
8. Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 27 and 32 of Catalano et al. co-pending Application No.10/492,059, also see US 2005/0043368 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compounds/composition and methods of use of formula (I), i.e.,



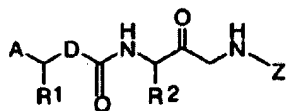
, wherein the variable A represents (Q³)-(Q²)_n-(Q¹)-(Q)_m- and the variable Q³ represents aryl or heteroaryl (e.g., thiazole, imidazole), the variable Z represents (X)_p-(X¹)_q-(Q¹)-(X²)- and the variable X² represents any or

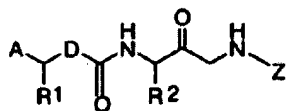
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heteroaryl (e.g., , see claim 1. Applicants compounds are for treating osteoporosis, see claim 1, 46 and 51 respectively.

Dependent claims 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 further limit a number of variable, i.e., m is 0 or 2.

Catalano et al. '059 claim a compounds/composition and method of use of



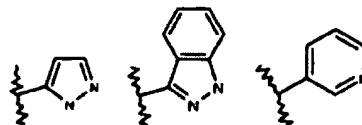
formula (I), i.e., , wherein the variable A represents (Q³)_p-(Q²)_n-(Q¹)-(Q)_m-, and the variable p, n or m is 0 independently, Q¹ represents aryl, heteroaryl (i.e., imidazole) or heterocyclyl, and the variable Z represents (X¹)_q (X²), the variable q is 0-2, and the variable X² represents aryl, heteroaryl or heterocyclyl, see columns 43-44. Catalano et al. compounds are used for treating osteoporosis, see claim 1, 27 and 32 respectively.

The difference between the instant claims and Catalano et al. is that the the variable Q¹ of Catalano et al. represents aryl, heteroaryl or heterocyclyl, while the instant claims represents aryl or heteroaryl at the same position.

One having ordinary skill in the art would find the instant claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 prima facie obvious **because** one would be motivated to employ Catalano et al. compounds/compositions and methods of use to obtain the

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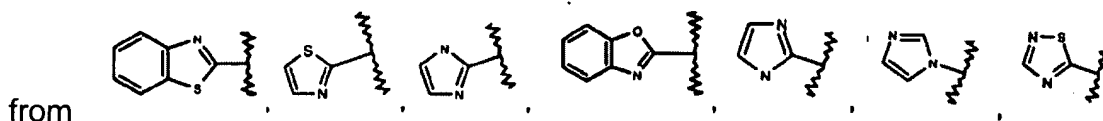
instant compounds/ compositions and methods of use, wherein the heteroaryl or




heterocyclyl of the variable X^2 is selected from

thereof; the

heteroaryl of the variable Q^3 is selected



or  thereof; the variables R^1 - R^4 or D independently do not represent

heteroaryl or heterocyclyl, the variables R^1 - R^4 or D independently are not substituted with heteroaryl or heterocyclyl. Dependent claims 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are also rejected along with claim 1 under the obviousness-type double patenting

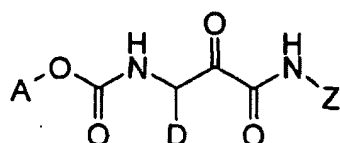
The motivation to obtain the claimed compounds derives from known Catalano et al. compounds/compositions would possess similar activity (i.e., treating osteoporosis) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

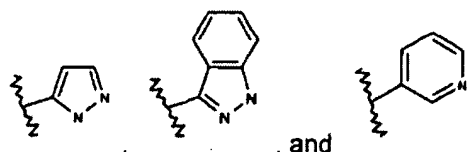
9. Claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 44 and 49 of Catalano et al. co-pending Application

No.10/510,469. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicants claim compounds/composition and methods of use of formula (I), i.e.,



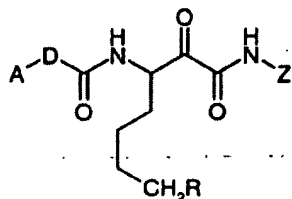
, wherein the variable A represents $(Q^3)-(Q^2)_n-(Q^1)-(Q)_m$ - and the variable Q^3 represents aryl or heteroaryl (e.g., thiazole, imidazole), the variable Z represents $(X)_p-(X^1)_q-(Q^1)-(X^2)$ - and the variable X^2 represents aryl or



heteroaryl (e.g., _____, _____, and _____); _____), see claim 1. Applicants
compounds are for treating osteoporosis, see claim 1, 46 and 51 respectively.

Dependent claims 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 further limit a number of variable, i.e., m is 0 or 2.

Catalano et al. '469 claim a compounds/composition and method of use of



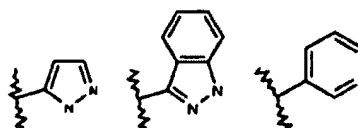
formula (I), i.e., $\text{C}_1\text{C}_2\text{N}$, wherein the variable A represents $(\text{Q}^4)_p-$
 $(\text{Q}^3)_n-(\text{Q}^2)_m-(\text{Q}^1)-$, and the variable p, n or m is 0-2 independently, Q^4 represents C_1-C_6
 alkyl, heterocyclyl or heterocyclylene (i.e., imidazole), and the variable Z represents

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(X)_m-(X¹) and the variable X¹ represents aryl, heteroaryl or heterocyclyl. Catalano et al. compounds are used for treating osteoporosis, see claim 1, 44 and 49 respectively.

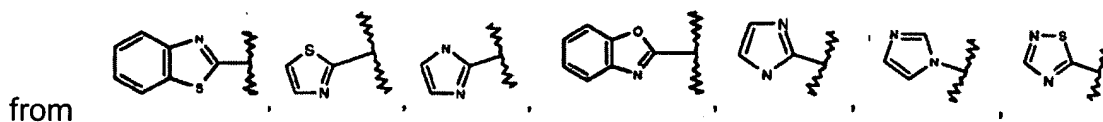
The difference between the instant claims and Catalano et al. is that the the variable Q⁴ of Catalano et al. represents C₁-C₆ alkyl, heterocyclyl or heterocyclylene, while the instant claims represents aryl, heteroaryl or heterocyclyl at the same position.


One having ordinary skill in the art would find the instant claims 1, 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 *prima facie* obvious **because** one would be motivated to employ Catalano et al. compounds/compositions and methods of use to obtain the instant compounds/ compositions and methods of use, wherein the heteroaryl or



heterocyclyl of the variable X² is selected from thereof; the

heteroaryl of the variable Q³ is selected



or  thereof; the variables R¹-R⁴ or D independently do not represent

heteroaryl or heterocyclyl, the variables R¹-R⁴ or D independently are not substituted with heteroaryl or heterocyclyl. Dependent claims 5-17, 19, 21, 28-29, 34-42, 44-48 and 51-52 are also rejected along with claim 1 under the obviousness-type double patenting

The motivation to obtain the claimed compounds derives from known Catalano et

al. compounds/compositions would possess similar activity (i.e., treating osteoporosis) to that which is claimed in the reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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A handwritten signature in black ink, appearing to read 'Robert Shiao', with a stylized flourish at the end.

Robert Shiao, Ph.D.
Patent Examiner
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December 15, 2006